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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,382	03/31/2000	Alison A. McCormick	LSB-001/CIP	9680
27860 7590 02/14/2007 LARGE SCALE BIOLOGY CORPORATION 3333 VACA VALLEY PARKWAY SUITE 1000 VACAVILLE, CA 95688			EXAMINER JOYCE, CATHERINE	
			ART UNIT	PAPER NUMBER
			1642	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/14/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/539,382	Applicant(s) MCCORMICK ET AL.	
	Examiner Catherine M. Joyce	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54,56,60-64,72,73,76,77 and 79-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54,56,60-64,72,73,76,77 and 79-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The Amendment filed November 15, 2006 in response to the Office Action of July 7, 2006 is acknowledged and has been entered. Claims 1-53, 55, 57-59, 65-71, 74-75, and 78 have been canceled, and claims 54, 56, 60-64, 72, 73, 76, 77 and 79-89 are under examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claims 82-86 and 89 remain rejected under 35 USC 112, second paragraph, for the reasons set forth previously in the Paper mailed July 7, 2006, Section 5, page 3.

Applicant argues that rejection is traversed but does not specifically argue any reasons for traversal. Applicant further states the claim has been amended to recite "a" polypeptide linker, and thus Applicant appears to attempt to overcome the rejection by this amendment.

Applicant's amendment to the claim has been considered but this amendment of the claim does not overcome the rejection of claims 82-86 and 89 under 35 USC 112, second paragraph, as being indefinite. The amendment of the claims to recite "a polypeptide linker which links two domains" does not relate the linker structurally to the polypeptide recited in claim 82, and thus the metes and bounds of the claims cannot be ascertained.

5. Claims 54, 56, 60-64, 72, 73, 76, 77 and 79-89 remain rejected under 35 USC 112, first paragraph, for the reasons set forth previously in the Paper mailed July 7, 2006, Section 6, pages 3-12.

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Applicant does not appear to argue the first aspect of this rejection, as set forth on pages 3-12 of the previous Office Action, wherein the Office Action provides that one of skill in the art could not predict that "(i) polynucleotides that encode any portion of a B-cell lymphoma surface immunoglobulin antigen, including any two domains or any portion of the VH region or any portion of VL region would be useful as a B-cell lymphoma tumor specific". Thus, no arguments are specifically considered here and the rejection is maintained as previously set forth.

With regard to the second aspect of this rejection, as set forth on page 12 of the previous Office Action, Applicant argues that no experimentation is required to determine which linker is the correct linker, the optimal linker or the right length, because the specification teaches, at paragraph 0036, that a linker can be between 1 and about 50 residues, sometimes between 3 and 25 residues and teaches, at paragraph 0037, that the linker can be between 2 and 12 different amino acids. Applicant further argues that the specification teaches, at paragraph 0111, that selection of (1) appropriate linkers and (2) the transient expression system ensure that the scFV molecules are secreted by the plant cells in a form that is folded in solution and in a conformation that resembles and mimics native IgV region domains on the subject's tumor cells that provided the genetic material for the scFV and that the scFV product is readily identified as the predominant secreted protein species in those plant cells into which it has been successfully incorporated, permitting simple selection and straightforward, rapid purification for use as a vaccine composition. Applicant argues that these statements teach that the polynucleotide is taken from the specific tumor for which the vaccine is intended and a randomized linker library is used, and that hundreds or even thousands of dual-domain polypeptides are encoded, with each polypeptide probably having a different linker, wherein the linkers differ in length and amino acid composition. Applicant further argues that the polynucleotides are then expressed in a plant and the vaccine is chosen from among those in the plants exhibiting the best expression, wherein each vaccine differs by the linker configuration.

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Applicant's arguments have been considered but have not been found to be persuasive. Although expression in a plant may select for functional linkers, as set forth in the previous Office Action, one of skill in the art could not predict that any size linker would produce functional idiotypes useful as a tumor-specific vaccine and thus one of skill in the art could not predict any starting population, with any sizes of linkers, could be used to produce functional idiotypes and one could not predictably distinguish between those polynucleotides that encode functional linkers and those that will not. Thus, one of skill in the art could not predict that the broadly claimed invention would function as contemplated in the specification:

Thus, the rejection of claims 54, 56, 60-64, 72, 73, 76, 77 and 79-89 under 35 USC 112, first paragraph, for the reasons set forth previously in the Paper mailed July 7, 2006, Section 6, pages 3-12, which reasons were not specifically traversed by Applicant, and for the reasons the reasons set forth previously in the Paper mailed July 7, 2006, Section 6, pages 12, wherein Applicant's arguments traversing the rejection are addressed in the paragraph above.

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

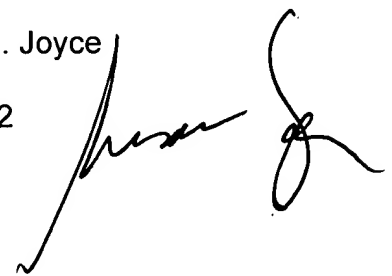
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine M. Joyce
Examiner
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A handwritten signature in black ink, appearing to read 'Catherine M. Joyce', is written over the typed name and title.